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Citation for published version:
McPhillips, R, Watson, D, Gao, J, Desmulliez, MPY, Vinnicombe, S, Cochran, S & Demore, C 2017, The fabrication and integration of a 15 MHz array within a biopsy needle. in *2017 IEEE International Ultrasonics Symposium (IUS).*, 8091764, IEEE International Ultrasonics Symposium, IEEE, 2017 IEEE International Ultrasonics Symposium, Washington, United States, 6/09/17.
https://doi.org/10.1109/ULTSYM.2017.8091764

Digital Object Identifier (DOI):
10.1109/ULTSYM.2017.8091764

Link:
Link to publication record in Heriot-Watt Research Portal

Document Version:
Peer reviewed version

Published In:
2017 IEEE International Ultrasonics Symposium (IUS)

The fabrication and integration of a 15 MHz array within a biopsy needle

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***Abstract* — It is proposed that integrating ultrasound transducer arrays at the tip of tools such as biopsy needles could enable valuable, real-time image feedback during interventional procedures. High-resolution ultrasound imaging has the potential to aid navigation of interventional tools, and to assist diagnosis or treatment via *in-vivo* tissue characterisation in the breast, amongst many other applications. In order to produce miniature transducer arrays incorporated within biopsy needle-sized packages (2 - 5 mm diameter), the challenges in micromachining and handling transducer materials at this scale must be overcome. This paper presents fabrication processes used in the micromachining of a 16 element 15 MHz PIN-PMN-PT piezocrystal-polymer composite array and its integration into an 11 G breast biopsy needle. Particular emphasis is given to the manufacturing of the 1-3 dice-and-fill piezocrystal composite, and establishing electrical interconnects. Characterisation measurements have demonstrated operation of each of the 16 elements within the needle case.**

Keywords— array, needle, ultrasound transducer; breast imaging

I. INTRODUCTION

Ultrasound (US)-guided biopsy is considered a cost effective and efficient means to acquire histopathological samples of suspicious masses within the breast. Accurate sonographic visualisation of the region of interest is a vital requirement for carrying out guided biopsy procedures in the breast. With the introduction of higher frequency ultrasound transducer arrays for high resolution imaging, the potential application of ultrasound in breast cancer diagnosis and staging has broadened considerably, not only for guidance of interventional biopsy needles, but with potential for *in-vivo* tissue characterisation [1] – [4].

Specific unmet clinical needs that could benefit from improved ultrasound imaging are the evaluation of pathology in the breast ducts to detect ductal carcinoma in-situ (DCIS) and diagnosis of low volume metastatic disease in the axilla. DCIS is the earliest form of breast cancer, and consequently detection and accurate sampling is crucial. Mammography remains the gold standard for detecting DCIS, but ultrasound technology is advancing such that systems operating above 13 MHz can reliably detect mammographically suspicious microcalcifications. Ultrasound imaging plays a supplementary role to mammography in the detection of benign ductal disease, as well as in the characterisation of focal masses and duct ectasia (blockages) [5] – [7]. For the diagnosis of DCIS, high resolution US has the potential to visualise internal calcifications of ducts and increase the accuracy with which suspicious ducts can be biopsied.

Effective characterisation of lymph nodes in the axilla adjacent to the breast is vital for determining cancer staging and prognosis. Metastatic deposits within axillary lymph nodes measuring less than 0.2 mm are called isolated tumor cells, and deposits between 0.2 and 2.0 mm are called "micrometastases" [8]. These levels of disease are not presently detectable using conventional ultrasound or mammography. Current examination techniques do not have the sensitivity or accuracy to exclude the standard of interventional assessment, such as sentinel lymph node biopsy and axillary lymph node dissection (ALND) [9]. Using high frequency (>15 MHz) ultrasound for visualisation and characterisation of micrometastases within lymph nodes could greatly aid diagnosis and management of the axillary nodes, and avoid unnecessary invasive clearance of the axilla via ALND.

As a means to improve clinical practice in these areas, it is proposed that a miniature high frequency ultrasound transducer array at the tip of a needle can provide precision guidance of a biopsy needle, maximising efficacy of sampling, and providing a minimally invasive means of in-vivo tissue characterisation. A high frequency transducer incorporated within a needle could be used to access the region of interest, overcoming the US penetration-resolution trade-off resulting from attenuation, and enabling high-

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resolution imaging regardless of the depth of these features below the skin. However, fabricating a miniature transducer array and integrating it within a needle requires not only a compact array design, but also reliable array fabrication techniques. To this end, this paper describes micromachining processes for fabricating piezocrystal composites and evaluates compact electrical interconnect approaches as two specific challenges in miniature array development.

II. ARRAY FABRICATION

A. *Device Design*

A fabrication process was developed to produce a 15 MHz 16-element array for the breast imaging application described above. The array is designed with 16 elements at 100 µm pitch, resulting in lateral dimensions of 1.6 mm length and 1 mm in width to allow for eventual incorporation within a needle of 2 mm inner diameter. The device design incorporates a 1-3 composite made with PIN(24%)-PMN-PT ternary piezocrystal material lapped to a thickness of ~117 µm, a quarter wavelength matching layer of 15% VF alumina loaded epoxy and an absorbing alumina loaded epoxy backing layer. The array is connected to a flexible printed circuit board (FPCB) with electrical interconnects created using an isotropic conductive adhesive. The FPCB has 50 µm tracks at 100 µm pitch and is designed to be twisted into a helix for insertion into an 8 cm long 11-gauge breast biopsy needle case.

B. *Dicing Process Development*

Composite piezoelectric substrates are generally favoured as the active material for ultrasound imaging transducers owing to their higher electromechanical coupling and lower acoustic impedance than bulk material [10][11]. For the 15 MHz array, the 1-3 composite development used the "dice and fill" method for creating the piezoelectric pillars. Dicing was carried out with a programmable precision dicing saw (MicroAce 66, Loadpoint, Swindon, UK) using a 13 µm diamond blade (Disco HI-TEC Europe, Munich, Germany). The pillars of the composite were diced at a pitch of 50 µm, to give a 57% VF composite, and to a depth greater than 200 µm. These dicing dimensions and the fragility of diced pillars mean that pillars often break, and whole rows of diced material can collapse, e.g. Fig. 1. Therefore, a key challenge in fabricating an array is to create a composite with 100% pillar yield, without collapse or damage across the active area of the array. Process variables such as spindle speed, feed rate, coolant flow and cut length affect the success of the dicing procedure. These variables were optimised experimentally to find a repeatable process for production of piezoceramic composites. Process development was carried out initially on CTS-3203-HD piezoceramic because it is less brittle than the piezocrystal, and provides a basis for the initial process optimisation prior to fine tuning for the more fragile PIN(24%)-PMN-PT. Plates of the material used for testing measured 3 x 1 mm^2.

The major sources of pillar breakage were found to be spindle speed and the blade feed rate. A higher spindle speed was possible in the ceramic in piezocrystal material. The blade feed rate needed to be adjusted between the first and second set of orthogonal cuts, as following the first pass, the material became increasingly delicate and benefitted from a reduced feed rate for the second pass.

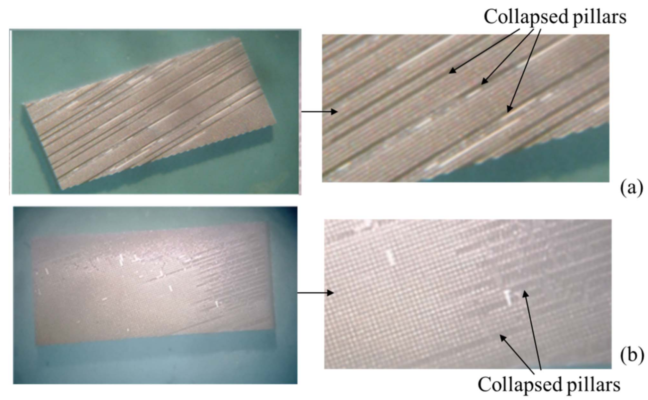

Fig. 1 Samples of piezoceramic material showing collapsed pillars following a) dicing in one direction and b) dicing in two orthogonal directions

The process parameters used in the program developed here enabled the two orthogonal dicing passes to be made without a filling step in between, producing a substrate with unsupported pillars. This allows the process time and the blade wear to be reduced because the blade does not need to pass through both epoxy and piezoelectric material for each cut of the second pass.

It was found that coolant should be at a flow rate less than 1 L/min to avoid damage to finely diced pillars, which can otherwise be washed away by the water flow. The flow rate was kept between 0.6 and 0.8 L/min. It was important to ensure that enough water was flowing over the blade to wash away material debris, and to keep the blade from over-heating. Being over-cautious and reducing the coolant blade wash below 0.6 L/min resulted in a build-up of residue on the blade and led to an increase in the kerf size. As a result, a compromise between minimising pillar damage yet sufficiently washing the blade and material debris was found.

C. *Dice-and-Fill Composite Results*

Once a repeatable process was established for the piezoceramic material, dicing trials using the piezocrystal material were undertaken. As the PIN(24%)-PMN-PT being considerably more brittle than the ceramic, the parameters of the ceramic dicing program caused significant damage to the single crystal composites pillars.

Spindle speed was set first at 35,000 rpm and reduced in 5000 rpm intervals to find a more suitable range, after which smaller adjustments were made in steps of 1000 rpm. Critically, the blade feed rate needed to be reduced further. This gave a significant improvement and reduced pillar damage by about 80%, limiting damage to pillars around the edge of the plate. Damage around the edges of the material was reduced further by increasing the path length, producing 100% yield of undamaged pillars, as shown in Fig. 2. The optimised program could be routinely used with no alterations or interruption. Details are given in Table 1.

TABLE I. DICING PARAMETERS USED FOR PRODUCTION OF CERAMIC AND SINGLE CRYSTAL 1-3 PIEZO-POLYMER COMPOSITES

	CTS3203 HD Piezoceramic		PIN-PMN-PT Single Crystal	
Parameters	**Pass 1**	**Pass 2**	**Pass 1**	**Pass 2**
Blade Kerf	0.013 mm	0.013 mm	0.013 mm	0.013 mm
Cut Depth	0.260 mm	0.230 mm	0.250 mm	0.230 mm
Number of Pecks	1	1	1	1
Pitch	0.050 mm	0.050 mm	0.050 mm	0.050 mm
Feed Rate	0.25 mm/s	0.20 mm/s	0.12 mm/s	0.12 mm/s
Spindle Speed	35,000 rpm	35,000 rpm	12,000 rpm	12,000 rpm

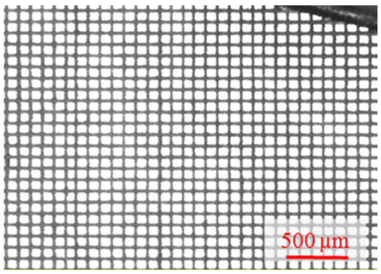

Fig. 2 PIN(24%)-PMN-PT material diced in consecutive orthogonal passes using a 13 µm blade at 50 µm pitch with no pillar damage

After filling with epoxy and lapping to 117 µm thickness, electrodes were deposited on both surfaces of the piezo crystal composite. Electrical impedance measurements (Fig. 3) demonstrate thickness mode resonance at 15.4 MHz and a unimodal response over the frequency range of interest.

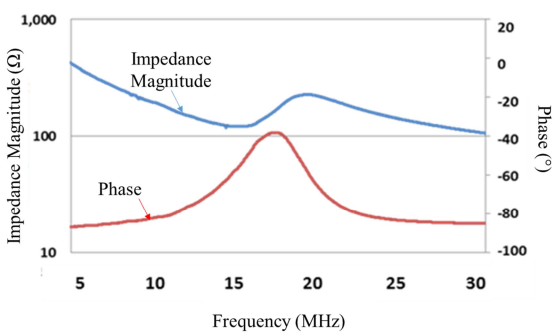

Fig. 3 Impedance magnitude and phase for the PIN24% PMN-PT composite material

III. INTERCONNECTIONS

The connection of the flexible circuit to the array proved to be the most challenging stage in the fabrication process. Two methods of connection were explored based on the use of FPCBs using a) isotropic adhesive, and b) anisotropic adhesive [12]. The method using the isotropic adhesive is discussed in this paper.

A. *Manual Bonding with Isotropic Adhesive*

The manual bonding method required manual alignment of the FPCB tracks to the array elements which were defined by scratch-dicing a blanket electrode deposited on the surface of the composite. The array elements were 50 µm wide with a gap of 50 µm between each element. The connection of the FPCB to the array elements was achieved using Ag-loaded conductive epoxy (RS Components, UK). As this conductive epoxy would connect across all elements, the dicing machine was used to dice through both the FPCB and the Ag-loaded connection in order to create 16 individual elements across the array at 100 µm pitch.

The technique involves manually aligning the element electrode tracks on the FPCB with the tracks on the array and securing the FPCB in place with tape. The FPCB is then gently pulled back, maintaining the alignment and the conductive epoxy is deposited between the two. The FPCB is then placed back on top of the array, where the conductive epoxy cures and secures it in place. The dicing saw is then used to dice through the adjacent connected tracks to establish separate connections for each array element

The initial challenge in this manual process was the alignment of the array elements to the FPCB tracks. This was overcome by securing the array with the defined electrode tracks facing upwards, to tape. This secured the array in place for the entire connection, bonding and dicing phases. Using a microscope (DinoCapture 2.0 USB), the FPCB was placed with tracks facing down, towards the array, onto the array elements. As the FPCB is transparent, the tracks could be seen to be overlapped with the array elements. It was important to ensure alignment was as accurate as possible to avoid any additive angular error across the area of overlap as this could cause shorting between elements.

When the conductive epoxy has been deposited, checking the alignment becomes difficult. Time is also limited following application of silver epoxy as this must be placed in an oven at 60 °C for 12 hours. The critical challenge was then in relation to dicing through the FPCB to retain the adhesion of such narrow tracks of the Ag-loaded epoxy. To further secure the FPCB tracks onto the array, a layer of cyanoacrylate adhesive (RS Components, UK) was spread across the bonding area prior to dicing.

B. *Interconnection Results*

Numerous tests were carried out on scratch diced arrays made from bulk ceramic to test the yield of separating conductive tracks using the dicing saw. A 50 µm thick blade was initially used to cut through the FPCB between the tracks, matching the track gap, but this caused the conductive epoxy to detach, and the FPCB tracks to fray away from the array elements. To maintain as large an area of contact of Ag-loaded epoxy as possible, smaller blades were chosen to cut along the middle of the 50 µm space between electrode tracks. In doing so, the 100 µm pitch was retained, while the maximum possible conductive epoxy was left to preserve adhesion. The successful process involved first dicing through the tracks of the FPCB and conductive epoxy in order to scratch dice and separate the electrode elements on the surface of the piezocomposite using a 19 µm kerf blade. On initial inspection, no damage to the conductive epoxy and FPCB was observed. To further secure the assembly however, a layer of cyanoacrylate adhesive (RS Components, UK) was spread such that it ran between the diced tracks. Subsequently, an additional series of cuts was made using a 13 µm kerf blade at a depth 5 µm deeper than the original cuts. This allowed any conductive debris to be cleared from the tracks and provided means to confirm separation of the tracks. By applying the additional adhesive between the tracks and then cutting with a smaller blade, a portion of adhesive remains on either side of the 13 µm kerf, along the length of the FPCB track, securing it in place, while ensuring that any connection between two adjacent tracks were avoided. This method proved successful and was used to bond the fabricated 15 MHz arrays to the flexible cabling.

IV. ARRAY MEASUREMENTS

The success of the bonding method is demonstrated with the pulse-echo response from elements in the packaged array, shown in Fig. 4. The array was submerged in water 5 mm away from a quartz flat reflector and the elements were connected, one at a time, to a pulser-receiver (DPR 500, JSR Ultrasonics, Pittsford, NY, USA). The signal response for an individual element in the array, recorded with a 30 dB gain, is shown in Figure 4 as an example. The center frequency is near the target 15 MHz, and the pulse has a 78% -6dB fractional bandwidth. These pulse-echo tests were carried out for all 16 elements, all of which were shown to be functional. The final connected and packaged device is shown in Fig. 5.

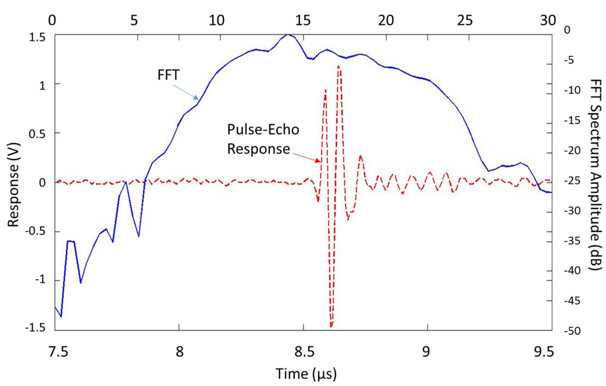

Fig. 4 Pulse-echo response of element number 6 from 15 MHz array

V. CONCLUSION AND FUTURE WORK

The results presented demonstrate fabrication processes developed for the production of a 16-element 15 MHz array within a breast biopsy needle. Further work has been undertaken to establish interconnects to high frequency arrays at this scale using alignment techniques requiring less manual intervention along with anisotropic conductive adhesive (ACA). The use of ACA removes the need for dicing through the electrical interconnect to separate elements. Additional testing is underway to connect the array to an imaging system in order to obtain real-time B-mode images and evaluate the potential of this array-in-a-needle approach to address the clinical challenges of image guidance and tissue characterisation for detecting and monitoring breast cancer.

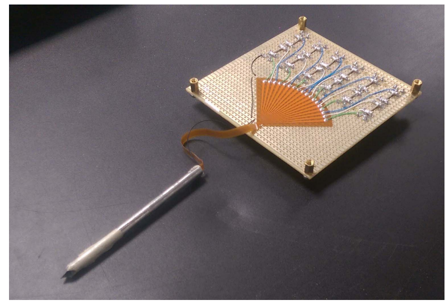

Fig. 5 15 MHz array with electrical connections incorporated into breast biopsy needle

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